UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff. *ex rel.* [SEALED] Plaintiff-Relators v. [SEALED] Defendants.	Case No. 1:18 CV 1732 Judge _____ **COMPLAINT AND JURY DEMAND** Filed Under Seal pursuant to 31 U.S.C. § 3730 (b)(2) JURY TRIAL DEMANDED

JUDGE BOYKO
MAG. JUDGE RUIZ

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff. *ex rel.* JUDITH GAU and JOHN DOE Plaintiff-Relators v. UNIVERSITY HOSPITALS HEALTH SYSTEM, INC. and DANIEL ELLENBERGER, Defendants.	)	Case No. _____ Judge _____ **COMPLAINT AND JURY DEMAND** Filed Under Seal pursuant to 31 U.S.C. § 3730 (b)(2) JURY TRIAL DEMANDED

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I. INTRODUCTION

1. This is an action filed under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, by Plaintiff-Relators Judith Gau and John Doe, on behalf of the United States of America and themselves, arising from false and/or fraudulent records, statements and claims made, used, presented and caused to be made used or presented by Defendants University Hospitals Health System, Inc. ("UH"), Daniel Ellenberger, and their affiliated or owned entities, agents, employees, and co-conspirators.

2. Defendants submitted bills to Government programs, including, but not limited to, Medicare, Medicaid, and Tricare to pay for Emergency Room medical services and follow-up services. Emergency Room services are administered to patients transported by local Emergency Medical Services ("EMS") agencies. The EMS agencies receive illegal kickbacks from Defendant UH, arranged by Defendant Ellenberger.

3. Defendants provide EMS Agencies expensive Durable Medical Equipment free of charge to induce or reward patient transports to UH Emergency Rooms. In many instances other Emergency Rooms may provide more convenient or closer locations for patients or provide more appropriate services.

4. Defendants are engaging in continuous and ongoing violations of the False Claims Act by certifying compliance with the Anti-Kickback Statute, despite providing valuable remuneration to sources of Emergency Room referrals.

5. The Government views compliance with the Anti-Kickback Statute as material to its decision to pay for health care claims, demonstrated in part through the requirement that

providers certify compliance with the Anti-Kickback Statute as a condition of payment under federal health care programs. *See* CMS Form 855B; CMS Form 1500.

II. JURISDICTION AND VENUE

6. This action arises under the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*.

7. This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331 and the False Claims Act confers nationwide jurisdiction and venue.

8. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service, because acts prohibited by 31 U.S.C. § 3729 occurred in this state, this judicial district, and division, particularly in Cuyahoga, Lake, and Geauga Counties, Ohio, and Defendants can be found, reside, or transact or have transacted business in Cuyahoga, Lake, and Geauga Counties, within the Northern District of Ohio, Eastern Division (Cleveland).

9. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) because Defendants regularly transact or have transacted business in this District, and did so at all times relevant to this Complaint and Defendants maintain offices in this jurisdiction. One or more acts proscribed in 31 U.S.C. § 3729 occurred in this District, including, but not limited to, fraudulent billing of Medicare and other Government funded health care programs for activities related to the provision of Emergency Room medical services and follow-up services.

10. As required by 31 U.S.C. § 3730(b)(2), a written disclosure of substantially all material evidence and information in Relators' possession was served on the Government on

May 11, 2018, *in camera* and under seal by delivering material evidence and information to the United States Attorney for the Northern District of Ohio.

11. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint is filed under seal and will remain under seal for a period of at least 60 days from its filing date or such date as is required by law or the Court so orders, and shall not be served upon Defendants unless the Court so orders.

III. PARTIES

A. Plaintiff-Relator Gau

12. Plaintiff-Relator Judith Gau has extensive experience in EMS Quality Assurance and as an EMS provider. She has over 25 years of experience in hospital administration and quality management, including nearly 15 years with Defendant UH. In July 2004, Ms. Gau began working for the UH EMS Training and Disaster Preparedness Institute, under the supervision of Defendant Daniel Ellenberger. Ms. Gau worked for 8 years as a licensed Emergency Medical Technician and Firefighter with the Valley Fire District in Peninsula, Ohio.

13. Ms. Gau's knowledge of the facts alleged herein was obtained through her direct experience during her UH employment under Mr. Ellenberger's supervision. She has extensive knowledge of UH's administrative systems, including locations of many relevant documents and topics discussed in medical director meetings. Her observations and conclusions are informed by her experience as an administrative and quality management professional and as a firefighter and EMS provider.

B. Plaintiff-Relator Doe

14. Plaintiff-Relator Doe has extensive experience as an EMS provider and training instructor. He worked as a Lieutenant at a Northeast Ohio Fire Department. In November 2009, he began working for the UH EMS Training and Disaster Preparedness Institute as a lead instructor, under Defendant Daniel Ellenberger's supervision. He worked for Defendant UH for almost 5 years. He continues to work in the EMS field in Northeast Ohio.

15. Mr. Doe's knowledge of the facts alleged herein was obtained through his direct experience during the course of his UH employment under Mr. Ellenberger's supervision. His observations and conclusions are informed by his experience as an EMS practitioner and instructor.

C. Defendant University Hospitals Health System, Inc.

16. Defendant University Hospitals Health System, Inc. ("UH"), is a leading healthcare provider in Northeast Ohio. Its corporate offices are at 11100 Euclid Avenue, Cleveland, Ohio 44106.

17. Defendant UH operates as a non-profit corporation and owns and operates 18 Emergency Rooms and 410 other facilities, including Medical Centers, Primary Care Locations, and Surgery Centers. UH's 12 medical centers have a total of 2,887 patient beds.

18. Defendant UH, as the term is used throughout this Complaint, encompasses all UH-owned, partially-owned, and related entities, including separately incorporated affiliates and all emergency care facilities owned or operated by Defendant UH, herein termed "UH Emergency Rooms." Where appropriate, individual UH-affiliated hospitals and entities are referred to separately.

D. Defendant Daniel Ellenberger

19. Defendant Daniel Ellenberger is the Director of the UH EMS Training and Disaster Preparedness Institute. He has been employed by UH since at least 1993. Mr. Ellenberger is the chief UH employee involved in purchasing and providing free durable medical equipment to local EMS agencies in exchange for steering emergency transport patients to UH facilities.

IV. APPLICABLE LAW

A. The False Claims Act

20. Originally enacted in 1863, the False Claims Act was substantially amended in 1986 by the False Claims Amendments Act. The 1986 Amendments enhanced the government's ability to recover losses sustained as a result of fraud against the United States. The Act was again amended in 2009 and 2010, further strengthening the law.

21. The False Claims Act provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the government for payment or approval is liable for a civil penalty of up to $21,916 for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1), (2). The False Claims Act empowers private persons who have information regarding false or fraudulent claims against the government to bring an action on behalf of the government and to share in any recovery. 31 U.S.C. § 3730(b)(1), (d). The complaint must be filed under seal without service on any defendant. 31 U.S.C. § 3730(b)(2). The complaint remains under seal while the Government

conducts an investigation of the allegations in the complaint and determines whether to join the action. 31 U.S.C. § 3730(a), (b)(4).

22. This suit is not based upon prior public disclosures found with sources of allegations or transactions that are encompassed by the definition of the term "publicly disclosed" under 31 U.S.C. § 3730(e)(4)(A), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010).

23. To the extent that a public disclosure has occurred, Ms. Gau and Mr. Doe qualify as original sources under the False Claims Act, as defined under 31 U.S.C. § 3730(e)(4)(B), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010). Relators possess direct and independent knowledge of the information as a result of their employment with Defendant UH, under the supervision of Defendant Ellenberger. Ms. Gau and Mr. Doe have voluntarily and affirmatively disclosed the allegations herein to the United States Government prior to filing this Complaint. See 31 U.S.C. § 3730(e)(4).

B. Federal Government Health Programs

24. The Federal government, through health programs such as Medicare and Medicaid, are among the principal payors for medical services rendered by Defendant UH at the hospitals and other medical facilities they own and operate. Medicare and Medicaid are administered by the Centers for Medicare and Medicaid Services (CMS), a federal agency which sets standards and regulations for participation in the programs.

25. Medicare is a Federal government program primarily benefitting the elderly that was created by Congress in 1965 when it adopted Title XVIII of the Social Security Act.

Medicare is administered by the Centers for Medicare and Medicaid Services. Medicare Part A covers medical care for patients admitted to the hospital, while Medicare Part B covers doctor's visits and medical care provided on an outpatient basis.

26. The Medicare program works by reimbursing health care providers for the cost of services and ancillary items at fixed rates. Reimbursements are made out of the Medicare Trust Fund. The Medicare Trust Fund is intended to reimburse health care providers, such as Defendant UH, only for those services that were actually performed, were medically necessary for the health of the patient, and were ordered specifically by a patient, using appropriate medical judgment and acting in the best interest of the patient. The Medicare Trust Fund relies on the representations of providers of Medicare services that the services billed by the providers are medically necessary for the patient, are actually performed as billed, and are compensable by Medicare. The other Government-funded programs operate in a similar fashion.

27. Medicare and other Government health care programs require that the service be physically performed and billed accurately according to CMS policies and procedure codes. CMS requires health care providers' certifications that they complied with all laws and regulations governing the provision of health care services, including compliance with anti-kickback laws and regulations. These certifications are an absolute condition precedent to retaining the Medicare funds conditionally advanced by the Government and a prerequisite to continued future participation in the Medicare program. Without such certification, Defendant UH is required to repay all Medicare and other Government health care payments previously received.

28. In order to be eligible for reimbursement from federal health care programs, services rendered, including ambulance transportation, must adhere to federal rules and

regulations. For ambulance services, this includes the requirement to transport each patient to the closest appropriate facility. *Medicare Claims Processing Manual*, Ch. 15, § 30.2.4. Claims submitted to federal health care programs for ambulance services and transportation to a UH emergency department that is farther than the closest appropriate facility are false claims. In many Ohio localities, Medicare and Medicaid patients account for a sizeable portion of all EMS transports.

C. The Anti-Kickback Statute

29. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), prohibits knowingly and willfully offering paying, soliciting, or receiving any remuneration to induce a person (a) to refer an individual to a person for the furnishing of any item or service covered under a federal health care program; or (b) to purchase, lease, order, arrange for, or recommend any good, facility, service, or item covered under a federal health care program. 42 U.S.C. § 1320a-7b(b)(1) and (2). A violation of the Anti-Kickback Statute constitutes a felony punishable by fines of up to $25,000 and imprisonment for up to five years.

30. Unlawful remuneration is broadly interpreted to include any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, for referrals, subject to specific exclusions. 42 U.S.C. § 1395nn(h)(1)(B); 42 C.F.R. § 411.351. Further, the Anti-Kickback Statute is violated if even one purpose of remuneration is to induce referrals, even if other, legitimate purposes are also present. *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985).

31. Compliance with the Anti-Kickback Statute is required for reimbursement of federal health care program claims, and claims made in violation of the law are actionable civilly

under the False Claims Act. 42 U.S.C. § 1320a-7b(g). Further, the United States has deemed violations of the Anti-Kickback Statute to be material to its decision to pay for health care claims, demonstrated in part through the requirement that providers certify compliance with the Anti-Kickback Statute as a condition of payment under federal health care programs. *See* CMS Form 855B; CMS Form 1500.

32. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of any individual or entity from participating in Medicare and Medicaid programs if it is determined that the party violated the Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended the Anti-Kickback Statute to include administrative penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, solicited, or received for a lawful purpose. 42 U.S.C. § 1320a-7a(a)(7).

33. Defendants' referral practices repeatedly violated the provisions of the Anti-Kickback Statute and False Claims Act because Defendants' improper kickbacks and incentives induced local EMS Agencies to transport patients to UH Emergency Rooms for medical treatment, when they otherwise would not have, and this treatment was paid for by Medicare and other Government funded health insurance programs.

D. HHS-OIG Identification of Donation Fraud Risk

34. The Department of Health and Human Services, Office of the Inspector General (HHS-OIG) has expressed longstanding concern with the provision of free goods and services to actual or potential referral sources. *See* HHS-OIG, Advisory Opinion No. 00-11 (Dec. 19, 2000).

In particular, the HHS-OIG recognized that "such arrangements are suspect and may violate the Anti-Kickback Statute if one purpose is to induce or reward referrals of Federal health care program business." *Id.*

35. The HHS-OIG has recognized that "[a] monetary donation by a hospital to a local ambulance company fits within the meaning of remuneration for purposes of the anti-kickback statute, if an intent to induce referrals of services or other business for which payment may be made under a Federal health care program is present." *Id.*

36. With regard to charitable donations, the HHS-OIG notes that "the substance of an arrangement--and not its characterization--ultimately determines its propriety under the anti-kickback statute." *Id.* In particular, "in some circumstances, payments characterized as 'donations' or 'grants' are nothing more than disguised kickbacks intended in part to induce or reward referrals, directly or indirectly." *Id.*

1. Ambulance Restocking Safe Harbor Does Not Apply

37. The Anti-Kickback Statute contains statutory exceptions and regulatory "safe harbors" that exclude certain conduct from the reach of the statute. See 42 U.S.C. § 1320a-7(b)(3); 42 C.F.R. § 1001.952. Safe harbor protection is only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. There is no such safe harbor applicable to Defendants' misconduct.

38. Hospitals and EMS agencies regularly enter into agreements that permit ambulance crews to restock medical supplies used in providing emergency medical care and transporting a patient to the emergency department. Such arrangements technically implicate the Anti-Kickback Statute.

39. HHS promulgated a safe harbor that protects certain *bona fide* restocking arrangements between hospitals and ambulance companies. 42 C.F.R. § 1001.952(v). The safe harbor "only applies to the gifting or transfer of drugs and supplies that replace comparable drugs and supplies administered by the ambulance provider (or first responder) to a patient before the patient is delivered to the receiving facility." 66 Fed. Reg. 62,979, 62, 979 n.1 (Dec. 4, 2001). Thus, Relators are not alleging that Defendants erred in providing *bona fide* restocking supplies and drugs.

40. The Anti-Kickback Statute safe harbor does not provide refuge for hospitals that provide free expensive durable emergency medical equipment to EMS agencies, particularly when the "gifts" are intended to induce patient referrals, as is the case here.

2. Advisory Opinions Relating to "Donations" as Kickbacks

41. HHS-OIG issues advisory opinions about the application of OIG's fraud and abuse authorities to a requesting party's existing or proposed business arrangement. 42 U.S.C. § 1320a-7d(b); 42 C.F.R. part 1008. One purpose of the advisory opinion process is for the HHS-OIG to provide meaningful advice on the application of the Anti-Kickback Statute in specific factual situations. These Opinions do not sanction in any way the misconduct occurring in Northeast Ohio where patients in trauma, with a health emergency, are having their emergency room location determined by which hospital has provided kickbacks to the local fire and emergency departments.

42. HHS-OIG issued several advisory opinions considering a variety of donation and charitable giving schemes. In general, the HHS-OIG noted several characteristics that suggest an

arrangement is a *bona fide* charitable donation and at low-risk for violating the Anti-Kickback Statute. These characteristics include:

(1) donations were modest in amount and one-time or fixed in duration;

(2) donations were not conditioned on the volume or value of referrals;

(3) donations furthered the charitable mission of the donor and donee entities; and

(4) the circumstances were such that the donee was not in a position to actually make or affect referrals to the donor.

43. In Advisory Opinion No. 00-11, HHS-OIG reviewed a proposed one-time charitable donation of up to $5,000 from Association A to EMS Service B to be used for the purchase of equipment and payment of paramedic training expenses. Association A operated a hospital, which receives approximately 73% of EMS Service B's transported patients. HHS-OIG opined that the proposed donation "presents a minimal risk of Federal health care program abuse, while providing significant benefits to the community." HHS reasoned that the scheme "presents little risk of overutilization" because Association A was not considering the number of patients requiring emergency transport and that the proposed one-time $5,000 payment was "relatively modest" and was not conditioned on referral volume or value. Finally, Association A and EMS Service B were both charitable entities sharing a common mission to be furthered by the proposed donation.

44. In Advisory Opinion No. 09-13, HHS-OIG reviewed a proposed Hospital transfer of paramedic services to an Ambulance Cooperative within the Hospital health system. The Hospital proposed to subsidize the Cooperative in cash, equipment, and services. HHS-OIG noted approvingly that "the Hospital's donations to the Ambulance Cooperative would not vary

with the volume or value of referrals to the Hospital by the Cooperative." In addition, because the Hospital was the only facility in the region, the Ambulance Cooperative was "not in a position to affect referrals . . . in a significant way." In these circumstances, the HHS-OIG concluded that "the risk of abuse is sufficiently low."

45. In contrast to the above Advisory Opinion situations, Defendant UH is not, by any means, the sole provider of emergency services in the area. Instead, in much of the Northeast Ohio region there is vigorous competition among hospitals for patients, including emergency room patients. Second, the kickbacks were not a one-time event and the *quid pro quo* nature of the equipment provided was clear. Third, the value of the kickbacks was substantial, as much as $ 20,000 for a single piece of equipment, amounts for medical director salaries and compensation, and other benefits.

E. Ohio Emergency Medical Services Regulations Generally Require Transport to the Closest Appropriate Facility

46. In Ohio, EMS medical care and transport practices are governed by comprehensive state law. *See, e.g.*, Ohio Admin. Code § 4765-14-05(A)(1)-(5) (outlining traumatic injury patients transport). Ohio law is aimed at the best choice for a patient (i.e., the nearest trauma center and the amount of time until care can be provided a patient), not the EMS agency's choice, except when there are issues of efficiency that might make the EMS agency unable to respond timely to another patient's emergency. In violation of these regulations, EMS agencies under UH's influence and under the medical direction of UH doctors frequently steer patients intentionally to a particular facility within the UH health care system.

47. Ohio law sets forth standards guiding EMS decision-making with regard to patient transport. In cases involving traumatic injuries, EMS personnel must transport patients to the nearest trauma center offering appropriate care. Ohio Admin. Code § 4765-14-05(A). EMS personnel may transport a trauma patient to an alternate facility only if:

(1) it is medically necessary;

(2) it is unsafe or medically inappropriate to transport the victim directly to the trauma center;

(3) it would cause a shortage of local EMS resources;

(4) the trauma center cannot provide care without undue delay; or

(5) the patient requests to be taken to a particular hospital.

Id. 4765-14-05(A)(1)-(5).

48. When a patient is not suffering from a traumatic injury, the Ohio Emergency Responder Guidelines provide that EMS personnel should select an appropriate medical facility, considering:

(1) time to definitive care;

(2) capabilities of receiving hospitals;

(3) patient wishes and family continuity; and

(4) efficient use of resources.

State of Ohio EMFTS Board, State of Ohio Emergency Responder Guidelines 14. There is no legal basis for transporting patients to a facility that has provided kickbacks to the EMS unit providing emergency services.

49. Ohio law requires that EMS agencies must designate a "medical director" who authorizes the agency to perform pre-hospital emergency medical services. Ohio Code § 4765.42; Ohio Admin. Code § 4765-1(PP).

50. Ohio EMS Medical Directors are generally emergency medicine specialists at local hospitals. An estimated 170 EMS agencies are under Defendant UH's medical direction. As of February 2018, UH lists 12 of its physicians as EMS Medical Directors. Among these, Dr. Robert Coleman, Dr. Howard Dickey-White, and Dr. Sheldon Rose are known to be involved in the kickback scheme.

51. Defendant UH frequently contributes to Medical Directors' compensation packages, thereby providing additional benefits to cooperating EMS agencies whose medical directors steer patients to UH facilities.

52. UH Medical Directors have contracts with each EMS agency for which they provide direction. The contract outlines the expectations and compensation for the Medical Director. According to a training guide from one of two medical director training courses approved by the Ohio Department of Public Safety, "The medical director should have authority over all clinical and patient care aspects of the EMS system or service, with the specific job description dictated by local needs." Ohio Chapter American College of Emergency Physicians, EMS Medical Directors' Course Ch. IV, at 1. The medical director must establish written protocols that EMS agencies must follow in rendering emergency medical services. Ohio Rev. Code § 4765.41. The Ohio Board of Emergency Medical Services charge Medical Directors with enforcing its treatment and transport rules and regulations. Ohio Admin. Code § 4765-14-03.

53. When EMS agencies submit claims to federal health care programs for emergency services and transport, they must comply with federal rules and regulations. Ambulance services are covered under Medicare Part B if the service meets the following conditions:

(1) Actual transportation of the beneficiary occurs;

(2) The beneficiary is transported to an appropriate destination;

(3) The transportation by ambulance is medically necessary;

(4) The ambulance provider/supplier meets all applicable vehicle, staffing, billing, and reporting requirements; and

(5) The transportation is not part of a Medicare Part A service.

Medicare Claims Processing Manual, Ch. 15, § 10.2. An "appropriate destination" is the closest appropriate facility. *Medicare Claims Processing Manual*, Ch. 15, § 30.2.4.

54. Under Ohio Medicaid regulations, the State will not pay for ambulance transportation that includes "excessive mileage resulting from the use of unnecessarily indirect routes." Ohio Admin. Code § 5160-15-26(A)(6). In addition, "claims for loaded mileage must not represent . . . more distance than was actually traveled." *Id.* § 5160-15-26(E).

V. FACTUAL ALLEGATIONS

A. Summary of Referral Scheme Allegations

55. Defendants use several strategies to induce referrals to UH emergency rooms and to select UH for medical director. By inducing EMS agencies to select UH doctors as medical directors, UH's steerage of patients becomes even more assured. The patient referral goal is

evident in, for example, a 2013 email from Mr. Ellenberger to Dr. Howard Dickey-White that Mr. Ellenberger was "looking at each hospital for opportunities to increase volume."

56. Dr. Dickey-White is a principal of 4M Management Systems and other 4M entities, which provide physician management and billing services to hospitals and medical clinics, including Defendant UH. He serves as the Chief Medical Officer of Island Medical Management. As a result of Dr. Dickey-White's relationships with these entities, he stands to benefit financially from increased referrals to UH emergency rooms.

57. As early as 2006, Defendants UH and Mr. Ellenberger arranged for UH to provide, without charge as "gifts," durable emergency medical equipment to local EMS agencies to induce or reward patient referrals to UH emergency rooms and selection of UH for medical direction. That scheme is ongoing.

58. Defendants' kickback scheme was intended to provide UH with a competitive edge over several other major hospital systems in Northeast Ohio. Notably, some patients in the area prefer Cleveland Clinic facilities, either because of its national and international reputation as a premier healthcare facility, because of its location in proximity to home or family, or because they had a preexisting relationship with Cleveland Clinic physicians. Other patients may prefer a nearby hospital where their personal physician has practice privileges or where they previously received care.

59. A large majority of hospital admission result from emergency transports. Therefore, influencing which emergency room is the destination for an emergency-transport patient can greatly impact UH's patient census and, in turn, its Medicare and Medicaid reimbursements.

60. UH experienced a record financial year in 2016. UH enjoyed a 11.5% increase in operating income in 2016, from $93.6 million in 2015 to $104 million in 2016. By comparison, Cleveland Clinic suffered a nearly 50% decrease in operating income in 2016, from $481 million in 2015 to $243 million in 2016. This disparity is due, at least in part, to the fraudulent equipment scheme operated by the Defendants to induce EMS transports to UH emergency rooms.

B. UH Provision of Free Equipment to EMS Agencies

61. Initially, emergency medical equipment provided to EMS units referring patients to UH emergency rooms were ostensibly part of a UH-led initiative to equip local EMS agencies with new equipment. Under Defendant Ellenberger's leadership, free equipment was almost exclusively used to induce EMS agencies to transport more patients to UH emergency rooms and to select UH physicians for medical direction.

62. UH's most frequently provided equipment is Lucas CPR devices and LifePak Monitor and Defibrillator units. As of April 2018, UH had provided, free of charge or other costs, at least 53 LifePak monitors and Lucas CPR devices to local EMS agencies. Donations continue to this day and are believed to number in the hundreds.

63. The Lucas CPR System is a battery-powered automatic chest-compression device designed to perform continuous CPR for up to 45 minutes. The current market value for a Lucas CPR device is up to $20,000.

64. The LifePak device is a cardiac monitor and defibrillator that is commonly used in emergency medical situations. The current market-value for a LifePak 15 Monitor and Defibrillator unit is up to $20,000.

65. Since 2009, Defendants provided kickbacks in the form of equipment "gifts" to EMS agencies in the following jurisdictions: Auburn, Aurora, Bainbridge, Bath, Beachwood, Bedford, Bedford Heights, Burton, Chagrin Falls, Chardon, Chester Township, Cleveland Heights, Concord, East Cleveland, Granger, Highland Heights, Highland Hills, Hiram, Hudson, Lyndhurst, Mantua, Montville, Munson, Newbury, North Olmsted, North Royalton, Northfield Center, Northfield Village, Orange, Pepper Pike, Richfield, Richmond Heights, Russell, Shaker Heights, Solon, Streetsboro, Thompson, Troy, Twinsburg, University Heights, Warrensville Heights, Westlake, and Woodmere.

66. In addition to the above equipment, UH provided some EMS agencies with free electrocardiogram monitors, valued at around $1500 each, and funding and equipment for emergency dispatch centers.

67. In September 2017, UH gave land valued at $372,000 to the City of Ashland (Ohio) to build a new fire and EMS station and funding for a new fire truck. Ashland is located about 20 miles from Akron, Ohio. On August 28, 2015, UH agreed to take control of Ashland's only hospital, Samaritan Medical Center. On the same day, Cleveland Clinic announced plans to take over Akron General Health System. UH's "gift" was intended to induce local EMS agencies to bring patients to UH Samaritan, rather than the much larger Cleveland Clinic at Akron General.

C. Defendants Promise Free Equipment to Induce Referrals From EMS Agencies

68. Defendants target EMS agencies that have low patient-transport volume to UH emergency rooms. Defendant Ellenberger and others at UH acting in concert with him pressure

those agencies to increase their transport volume by promising gifts of Lucas CPR machines or LifePak devices.

69. Defendants UH and Ellenberger provide equipment in exchange for a promise from the EMS agency that it will increase future transports to UH facilities.

70. Defendants UH and Ellenberger establish quotas that EMS agencies must meet to receive the equipment. For example, in 2015, Mr. Ellenberger promised equipment to the Valley Fire District EMS in Peninsula, Ohio, if it brought at least 5 patients to UH per month. In 2013, Valley Fire District EMS transported only 16 patients to UH emergency rooms. To date, Defendants have not provided Valley Fire District EMS with any equipment because it failed to meet its quota.

71. Concord Township EMS received a Lucas 2 CPR machine on December 12, 2012. In 2013, the EMS agency transported more than twice the number of patients to UH Geauga Emergency Department than in 2012 (58 in 2012 and 136 in 2013). UH Geauga is 12 miles (22 minutes of travel time) away from the closest Concord Township Fire Station. By comparison, the Lake Health Tripoint Emergency Room, which opened in October 2009, is just 2.3 miles (7 minutes) away. The dramatic change in transport volume between 2012 and 2013 was due to EMS personnel and UH EMS medical director decisions to steer patients to UH.

72. In addition to the anti-kickback law violations, UH's scheme to steer patients to its more distant facilities endangers patients and even the general public traveling on the roadways unnecessarily used. It causes EMS agencies to overcharge insurance companies, including federal healthcare programs, for miles traveled with the patient ("loaded mileage").

D. Defendants Retaliate Against EMS Agencies That Refuse to Steer Patients, Showing that UH Provides "Free" Equipment and Supplies As Kickbacks for Patient Referrals

73. When promises of equipment (a "carrot") are not enough to entice an EMS agency to increase its UH transport volume, Defendants use a "stick" by withdrawing UH support for emergency medical personnel training and continuing education. These tactics are strong evidence of UH's illegal intent in providing "free" medical equipment to those EMS agencies that cooperate with the patient steering kickback scheme.

74. Defendant Ellenberger refused to provide the Twinsburg, Hiram, and Plymouth EMS agencies with the usual meals and snacks during UH-sponsored EMS continuing education symposia because the agencies did not steer patients to UH emergency rooms.

75. Defendant Ellenberger withheld the Hiram EMS agency's drug license for several months because its UH transport volume was, in his determination, too low. The agency's UH-transport volume fell from 76 in 2011 to 46 in 2013. The low volume and the retaliation resulted in part from Hiram changing its EMS medical direction from UH to another hospital in August 2012.

76. In 2013, Defendant Ellenberger refused to provide Twinsburg with new QuikClot packs (a hemostatic sponge containing a natural mineral that acts as a clotting agent) to replace expired ones. QuikClot packs cost less than $20.

77. Defendant Ellenberger treated the Twinsburg EMS agency particularly harsh because, after contracting with UH for medical direction and receiving an equipment gift, the agency refused to steer patients to the UH Twinsburg Emergency Department. When a Cleveland Clinic emergency room opened in Twinsburg in July 2011, the number of patient transports to

UH dropped from 684 in 2009 to just 337 in 2012. In August 2012, Defendant Ellenberger complained, "We are getting our a___es handed to us in Twinsburg which means we need a constant presence."

E. Defendants Reward EMS Agencies with Additional Kickbacks When EMS Agencies Exceed UH's Patient Volume Quotas

78. Defendants UH and Ellenberger rewards EMS agencies that make a high volume of patient transports to UH facilities with additional equipment gifts and favorable treatment.

79. The Bedford and Richmond Heights EMS agencies receive preferential treatment from Defendant Ellenberger because they have been under UH medical direction for a long time and continue to increase patient transports to UH emergency rooms. Defendant Ellenberger hired three Richmond Heights EMS paramedics to work for the UH EMS Institute on a part-time basis. Unlike other UH employees, these individuals get reimbursed by UH for trips to conferences.

F. Defendants' Medical Directors Monitor and Pressure EMS Agencies to Cooperate with the Patient-Steering and Kickback Scheme

80. Defendants UH and Ellenberger offer free equipment to encourage EMS agencies to contract with UH for medical direction.

81. Defendants use free equipment and medical directorships to foster a culture of indebtedness among EMS agencies toward UH. EMS agencies feel obligated to bring patients to UH emergency rooms to obtain more equipment and avoid harsh treatment from Defendant Ellenberger.

82. EMS agencies that select UH for medical direction and are promised or receive equipment gifts greatly increase the volume of patients they transport to UH emergency rooms.

83. In a presentation to the Ravenna Township Board of Trustees, Defendants explicitly offered a Lucas CPR device and other benefits in exchange for the town's EMS agency contracting with UH for medical direction.

84. Defendant Ellenberger delivered the same message in a presentation to Eaton Township: "[UH] provide[s] equipment that the EMT's (sic) need in the field at no charge to the community."

85. Once the EMS agency agrees to medical direction, UH uses its medical directors to directly pressure agencies to make more patient transports to UH emergency rooms.

86. For example, the Twinsburg EMS agency's UH medical director, Dr. Robert Coleman, and Defendant Ellenberger explicitly instructed the agency to transport more patients to UH emergency rooms, particularly after the Twinsburg Cleveland Clinic emergency room opened. Defendants provided Twinsburg EMS with a Lucas device on November 18, 2014, in an attempt to induce it to transport more patients to UH facilities.

87. Between 2010 and 2013, numerous agencies under UH medical direction received costly "free" equipment designed to induce or reward referrals. As the table below shows, Defendants rewarded or induced EMS agencies under UH medical direction to steer patients to UH, based on the total number of patient-transports to UH facilities each year:

EMS Agency	2010	2011	2012	2013	Kickbacks
Chagrin Falls	2	119	151	156	Received a Lucas device on January 14, 2014, as a reward for steering patients to UH.
Concord	12	36	58	136	Received a Lucas device on December 1, 2012, to induce steering patients to UH.
Orange	34	206	213	223	Received a Lucas device on March 4, 2013, as a reward for steering patients to UH.

Richmond Heights	600	558	827	906	Received a Lucas device on May 14, 2013, as a reward for steering patients to UH.
Shaker Heights	490	725	681	794	Received a Lucas device on December 16, 2013, as a reward for steering patients to UH.
Solon	184	245	303	583	Received a Lucas device on April 15, 2013, as a reward for steering patients to UH.
Streetsboro	95	146	195	344	Received a Lucas device on March 23, 2015, and a LifePak 15 on December 19, 2016, as rewards for steering patients to UH.

G. Defendants Provide "Free" Equipment Based on Patient Referral Volume

88. The local EMS community is well aware that "free" equipment from UH is contingent on a high transport volume to UH emergency departments.

89. In 2015, Mr. Ellenberger refused to provide equipment to Valley and Twinsburg EMS agencies "until they bring there [sic] quota up [per] month on bringing patients to UH facilities." Around the same time, the Kingsville EMS agency inquired about whether "their call volume is high enough to get a Lucas device that [UH] is passing out."

90. An EMS supply company in the Niles, Ohio-area cut ties with Defendants because of Defendants' business practices, including only offering equipment "gifts" commensurate with an agency's transport volume.

H. Defendants Track Patient Transport Volume

91. UH reports show increases in patient transport immediately before or after an EMS agency receives free equipment and after they switch medical direction to UH.

92. UH monitors patient transport volumes by each EMS agency to any emergency room through cloud-based reporting software, which it provides free to EMS agencies. Mr.

Ellenberger receives transport volume information from UH staff when the staff visits different facilities.

93. Each UH emergency department produces annual reports documenting the number of patient transports by EMS agency and comparing annual volume to previous years.

I. Defendants Conceal Funding for Equipment Kickbacks

94. The medical equipment provided to the EMS agencies in the referral scheme is purchased through UH's community benefit fund, ostensibly designed to support community health improvement, charity care, Medicaid shortfalls, training, and research. The IRS requires non-profit hospitals to demonstrate community benefit to maintain their tax-exempt status.

95. Defendant UH publicized funds raised for Lucas CPR devices and at least one facility listed the equipment "gifts" on IRS Form 990 regarding community benefit activities.

96. Yet, Defendants sought to conceal the equipment "gifting"scheme. Under the hospital's capital purchase plan, UH requires internal approval above Mr. Ellenberger's level for all expenditures of $ 5,000 or more. Because Lucas CPR devices and LifePak 15 Monitor and Defibrillator units cost well over $ 5,000, an internal approval is needed for each purchase. Defendants neither sought nor obtained these approvals.

97. Defendants Ellenberger and UH conceal the individual equipment purchases by splitting them into multiple invoices. The November 2014 Statement of Operations for the UH EMS Institute reports purchases of a LifePak 15 Monitor and Defibrillator and a Lucas 2 as four separate invoices: three for $4,995 and one for $2,742.14. The invoices all relate to a single purchase, described as "Quote 1-270."

J. Defendant UH's Compliance Department Affirmed Relators' Whistleblowing and Recommended an Internal Audit in 2014

98. In 2014, Relators complained to the UH Compliance Department about Mr. Ellenberger's equipment "gifting" scheme. UH was thus aware of the kickback allegations made in this Complaint and the inconsistencies and gaps in documentation regarding equipment purchased and the equipment "gifts" made. No comprehensive internal audit was done, despite the Anti-Kickback Statute implications. UH did not take further action to monitor the free equipment scheme or accompanying inducements to EMS agencies.

99. Nevertheless, around the same time, Defendants created back-dated charitable gift agreements. This was an attempt to conceal unlawful kickbacks.

VI. SCOPE OF FALSE CLAIMS

100. The kickback scheme taints all claims for services provided by UH to illegally referred patients for whom the federal government is the primary payor. This includes emergency department treatment following EMS transport, as well as follow-up procedures and continuing care.

101. For example, a Medicare patient transported to a UH emergency room for a heart attack results in claims to Medicare for immediate treatment for stabilization, hospitalization, near-term bypass or open heart surgery, and long-term follow-up and health maintenance. It is likely that, despite the illegal referral, the patient will continue to utilize UH facilities for his future care. All claims for payment from Medicare for this patient are false claims.

102. According to Centers for Medicare and Medicaid Services data, Medicare on average spends about the same per patient for an episode of care at most UH hospitals as it does

across all inpatient hospitals nationally. For a heart attack patient, Medicare pays UH hospitals about the national average of $23,119. This does not include long-terms follow-up care or other future services the patient receives at UH in the interest of keeping his records within one hospital system.

103. Defendants' kickback scheme causes northeastern Ohio EMS agencies to overbill federal health care programs for ambulance transports. To fulfill quotas set by Defendants UH and Ellenberger, EMS agencies frequently must transport patients greater distances than is medically, legally, or otherwise appropriate to reach UH emergency rooms. The extra distance traveled from the patient pick-up location to a UH emergency room directly increases the total claim because reimbursement is based on mileage driven.

VII. VIOLATIONS OF THE FALSE CLAIMS ACT

COUNT I
False Claims Act - Presentation of False Claims
31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A) as amended in 2009

104. The allegations in the paragraphs above are hereby re-alleged and set forth fully as above.

105. As detailed above, Defendants repeatedly acted to violate the False Claims Act, 31 U.S. C. § 3729(a)(1), and, as amended, 31 U.S.C. § 3729(a)(1)(A), and their conduct is ongoing.

106. As detailed above, Defendants knowingly violate laws and regulations by providing medical equipment to EMS agencies to induce patient transports to Defendants' emergency medical facilities.

107. This scheme violates the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

108. The Anti-Kickback Statute makes it illegal to pay or to receive remuneration for referrals under the circumstances set forth above.

109. A violation of the Anti-Kickback Statute is also a violation of the False Claims Act.

110. Therefore, Defendants are liable for each and every claim made by any UH entity as a result of a referral in violation of the Anti-Kickback Statute including but not limited to facility fees and physician fees.

111. Through the above practices, Defendants submit or cause to be submitted false claims to the United States and are liable for three times the amount of damages created by each and every such false claims made to the Government of the United States.

112. Each and every such fraudulent claim is also subject to a civil fine under the False Claims Act of $11,181 to $22,363, plus any increase as specified under the Federal Civil Penalties Adjustment Act of 1990.

COUNT II
False Claims Act - Making or Using False Record or Statement to Cause Claim to Be Paid 31 U.S.C. § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B), as amended in 2009

113. The allegations in the paragraphs above are hereby re-alleged and set forth fully as above.

114. In furtherance of the illegal activities described herein, Defendants necessarily create false records material to supporting false claims in violation of 31 U.S.C. § 3729(a)(1)(B) and their conduct is ongoing.

115. False records created by the Defendants include, but are not limited to, false certification of compliance with the Anti-Kickback Statute.

116. Defendants are liable for three times the amount of damages created by each and every such false claims made to the Government of the United States.

117. Each and every such fraudulent claim is also subject to a civil fine under the False Claims Act of $11,181 to $22,363, plus any increase as specified under the Federal Civil Penalties Adjustment Act of 1990.

COUNT III
False Claims Act - Conspiracy
31 U.S.C. § 3729(a)(3), 31 U.S.C. § 3729(a)(1)(C), as amended in 2009

118. The allegations in the paragraphs above are hereby re-alleged and set forth fully as above.

119. UH and Mr. Ellenberger, as well as UH medical directors, work together to induce EMS agencies to transport patient to UH facilities to obtain payments from Government programs in violation of 31 U.S.C. § 3729(a)(1)(C) and their conduct is ongoing.

120. As conspirators, UH and Mr. Ellenberger are jointly and severally liable for all claims generated by the conspiracy, including those under the Anti-Kickback Statute and the Stark law, which prohibits physicians from self-referring patients, such as the referrals made by the UH EMS medical directors to the UH emergency rooms.

121. Each and every such fraudulent claim is also subject to a civil fine under the False Claims Act of $11,181 to $22,363, plus any increase as specified under the Federal Civil Penalties Adjustment Act of 1990.

PRAYER FOR RELIEF

WHEREFORE, Relators requests that judgment be entered against Defendants, ordering that:

1. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, *et seq.*;

2. Defendants pay not less than $11,181 and not more than $22,363 for each violation of 31 U.S.C. § 3729 plus any increase as specified under the Federal Civil Penalties Adjustment Act of 1990 and three times the amount of damages the United States has sustained because of Defendants' actions;

3. Relators be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d);

4. Relators be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d);

5. Relators be provided with injunctive or equitable relief, as may be appropriate, to prevent further harm to themselves and to prevent the harm to others and the public caused by Defendants' retaliation against whistleblowers;

6. Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

7. Defendants disgorge all sums by which they have been enriched unjustly by its wrongful conduct;

8. Relators be awarded all other damages to which they are entitled, including compensatory and punitive damages; and

9. The United States and Relators recover such other relief as the Court deems just and proper.

Respectfully submitted,

Ann Lugbill by RR

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REQUEST FOR TRIAL BY JURY

Relators hereby demands a trial by jury.

Ann Lugbill by R.R.
Ann Lugbill

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of July 2018, a copy of the foregoing Complaint was mailed for filing *in camera* and under seal pursuant to the False Claims Act. The Complaint, along with a copy of the False Claims Act Disclosure, will be served upon the following individuals as indicated below.

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